

§ 558.265

21 CFR Ch. I (4–1–02 Edition)

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(B) 5 mg/kg body weight (2.27 mg/lb) in a free-choice feed.	.....	As in paragraph (e)(3)(i)(A) of this section.	Formulate as specified in paragraph (e)(3)(ii) of this section. Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Do not slaughter within 13 days following last treatment.	057926

(ii) *Formulate for use as a free-choice cattle feed as in paragraph (e)(3)(i)(B) of this section as follows:*

Ingredient <sup>1</sup>	Percent	International feed No.
(A) Ingredient: .....		
Copper sulfate .....	0.45	6–01–720
Dried Cane Molasses .....	3.12	4–04–695
Monosodium phosphate .....	31.16	6–04–288
Salt (sodium chloride) .....	59.00	6–04–152
Zinc sulfate .....	0.76	6–05–556
Fenbendazole Type A article (20%) .....	5.51	
(B) Ingredient: .....		
Dicalcium phosphate .....	32.31	6–00–080
Limestone .....	17.13	6–02–632

Ingredient <sup>1</sup>	Percent	International feed No.
Magnesium oxide .....	9.79	6–02–756
Zinc sulfate .....	1.47	6–05–556
Copper sulfate .....	0.29	6–01–720
Potassium iodide .....	0.0098	6–03–759
Dried Cane Molasses .....	0.98	4–04–695
Selenium .....	0.0002	
Salt .....	35.93	6–04–152
Fenbendazole Type A article (20%) .....	2.09	

<sup>1</sup>The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium must comply with published regulations.

(4) *Zoo and wildlife animals.*

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine ( <i>Sus scrofa</i> ).	3 mg/kg/day for 3 days..	For the removal and control of kidney worm ( <i>Stephanurus dentatus</i> ), roundworm ( <i>Ascaris suum</i> ), nodular worm ( <i>Oesophagostomum dentatum</i> ).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae).	2.5 mg/kg/day for 3 days..	For the removal and control of small stomach worm ( <i>Trichostrongylus</i> spp.), thread necked intestinal worm ( <i>Nematodirus</i> spp.), barberpole worm ( <i>Haemonchus</i> spp.), whipworm ( <i>Trichuris</i> spp.).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926
(iii) Rocky mountain bighorn sheep ( <i>Ovis c. canadensis</i> ).	10 mg/kg/day for 3 days..	For the removal and control of <i>Protostrongylus</i> spp.	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926

[66 FR 58935, Nov. 26, 2001]

§ 558.265 **Halofuginone hydrobromide.**

(a) *Approvals.* Type A medicated articles: 6 grams per kilogram (2.72 grams

per pound) to 057926 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.308 of this chapter.

(c) *Conditions of use.* (1) It is used in feed for broiler chickens as follows:

(i) *Amount.* 2.72 grams per ton.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bambermycins 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers.

(iii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(iv) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 to 15 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(v) *Amount per ton.* Halofuginone hydrobromide 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams and roxarsone 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E.*

*brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain; and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; use as sole source of organic arsenic; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vi) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, *E. maxima* and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus lincomycin 2 to 4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima* and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(viii) *Amount per ton.* Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

(2) It is used in feed for turkeys as follows:

(i) *Amount per ton.* 1.36 to 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*.

(B) *Limitations.* Feed continuously as sole ration; withdraw 7 days before slaughter; do not feed to layers or water fowl; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone hydrobromide 1.36 to 2.72 grams plus bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl. Keep out of lakes, ponds, and streams. Halofuginone is toxic to fish and aquatic life. Halofuginone is an irritant to eyes and skin. Avoid contact with skin, eyes, or clothing.

(iii) *Amount per ton.* 1.36 to 2.72 grams of halofuginone hydrobromide plus 2 grams of bambermycins.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide is toxic to fish and other aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an eye and skin irritant. Avoid contact with skin, eyes, and clothing.

(3) It is used in feed for replacement cage laying chickens and replacement broiler breeder chickens as follows:

(i) *Amount per ton.* 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. mivati*/*E. mitis*, and *E. brunetti*.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replace-

ment broiler breeder chickens until 16 weeks of age. Withdraw 4 days before slaughter. Do not feed to laying chickens or water fowl. Halofuginone hydrobromide is toxic to fish and aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an irritant to eyes and skin. Avoid contact with skin, eyes, and clothing.

(ii) *Amount per ton.* Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

[50 FR 33719, Aug. 21, 1985, as amended at 50 FR 42518, Oct. 21, 1985; 51 FR 7397, Mar. 3, 1986; 51 FR 11439, Apr. 3, 1986; 51 FR 14989, Apr. 22, 1986; 51 FR 23737, July 1, 1986; 53 FR 1018, Jan. 15, 1988; 53 FR 11065, Apr. 5, 1988; 54 FR 11519, Mar. 21, 1989; 54 FR 28052, July 5, 1989; 59 FR 51498, Oct. 12, 1994; 61 FR 21076, May 9, 1996; 61 FR 24694, May 16, 1996; 64 FR 42597, Aug. 5, 1999; 65 FR 45712, July 25, 2000; 66 FR 47962, Sept. 17, 2001]

#### § 558.274 Hygromycin B.

(a) *Approvals.* (1) Type A medicated articles: 2.4 and 8 grams per pound to 000986 in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(2) 2.4 grams per pound to 043733 in § 510.600(c) of this chapter for use in swine feed as in paragraph (c)(1)(ii) of this section.

(3) [Reserved]

(4) 0.6 gram per pound to 017790, 043733, and 050639 in § 510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section and in swine as in paragraph (c)(1)(ii) of this section.

(5)–(6) [Reserved]